K123798

510(k) Summary
Liquichek Diabetes Control

JAN 0 9 2013

1.0 Submitter

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Contact Person

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Date of Summary Preparation

December 21, 2012

2.0 Device Identification

Product Trade Name:	Liquichek Diabetes Control
Classification Panel:	Clinical Chemistry
Common Name:	Single (Specified) Analyte Controls (Assayed and Unassayed)
Classification:	Class I, Reserved
Product Code:	JJX
Regulation Number:	21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Diabetes Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K052838

4.0 Description of Device

This product is prepared from human whole blood and contains preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Liquichek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analyte listed in the package insert.

7.0 Comparison of the new device with the Predicate Device

Liquichek Diabetes Control claims substantial equivalence to the Liquichek Diabetes Control currently in commercial distribution (K052838). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Liquichek Diabetes Control *(New Device)*	Liquichek Diabetes Control *(Predicate Device, K052838)*
Similarities		
Intended Use	Liquichek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analyte listed in this package insert.	Liquichek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analyte listed in this package insert.
Matrix	Human Whole Blood	Human Whole Blood
Form	Liquid	Liquid
Thawed Opened Stability	14 days at 2 to 8°C	14 days at 2°C to 8 °C
Thawed Unopened Stability	180 days at 2 to 8°C	180 days at 2 to 8°C
Differences		
Fill Volume	2 mL	1 mL
Storage unopened (Shelf life)	-10°C to -50°C until expiration date	-10°C to -70°C until expiration date
Analytes	• Hemoglobin A1C	• Hemoglobin A1C • Hemoglobin

8.0 Statement of Supporting Data

Real-time stability studies were conducted to establish the thawed stability claims (open-vial and unopened). Accelerated stability studies were conducted to establish the shelf-life claims at -20 to -50 °C. Based on the available data, product claims are as follows:

- Thawed Open Vial Stability: 14 days at 2°C to 8 °C
- Thawed Unopened Stability: 180 days at 2°C to 8 °C
- Shelf Life Stability: 3 years at -10°C to -50°C

9.0 Conclusion

Based on the performance characteristics indicated above, Bio-Rad's Liquichek Diabetes control is substantially equivalent to the predicate device k052838.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 9, 2013

Bio-Rad Laboratories
c/o Suzanne Parsons
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k123798
Trade/Device Name: Liquichek Diabetes control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, Reserved
Product Code: JJX
Dated: December 7, 2012
Received: December 10, 2012

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123798

Device Name: **Liquichek Diabetes control**

Indications for Use: Liquichek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analyte listed in the package insert.

Prescription Use __X____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123798